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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte DAVID HUNG

Appeal 2008-2336
Application 09/912,499
Technology Center 3700

Decided: July 22, 2008

Before ERIC GRIMES, LORA M. GREEN, and FRANCISCO C. PRATS, *Administrative Patent Judges*.

PRATS, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a device for collecting breast duct fluid. The Examiner has rejected the claims as anticipated and obvious. We have jurisdiction under 35 U.S.C. § 6(b). We affirm-in-part.

STATEMENT OF THE CASE

Claims 1-8, 10-13, 26, and 27 are pending and on appeal (App. Br. 2). Claim 1 is representative of the claimed subject matter and reads as follows:

> 1. A device for collecting breast duct fluid from within a breast duct in order to detect breast cancer or precancer comprising:
>
> a probe having a diameter sized to access a breast duct and a distal portion being capable of contacting an interior lumen of a breast duct and retrieving a sample of the breast duct fluid from within the duct for analysis, and wherein said probe is free of an opening through which a fluid from an external source can be introduced into said probe and pass through said probe into the duct when said probe is positioned within the breast duct, and wherein said probe is rigid before entry into the breast duct, and flexible upon resistance in the duct.

The Examiner relies on the following documents as evidence of unpatentability:

Nicholson	US 4,616,656	Oct. 14, 1986
Butler	US 4,767,011	Aug. 30, 1988
Marchosky	US 4,947,842	Aug. 14, 1990
Raynor	US 5,003,905	Apr. 2, 1991
Pestes	US 5,623,942	Apr. 29, 1997
Jones	US 6,101,635	Aug. 15, 2000
Kurz	US 6,319,267 B1	Nov. 20, 2001
Hung	US 6,391,026 B1	May 21, 2002

The following rejections are before us for review:

Claims 1-6, 12, and 13 stand rejected under 35 U.S.C. § 102(b) as anticipated by Pestes (Ans. 4).

Claims 26 and 27 stand rejected under 35 U.S.C. § 103(a) as being obvious in view of Pestes (Ans. 5).[1]

Claims 7, 8, and 10 stand rejected under 35 U.S.C. § 103(a) as being obvious in view of Pestes and Nicholson (Ans. 5).

Claim 11 stands rejected under 35 U.S.C. § 103(a) as being obvious in view of Pestes and Marchosky (Ans. 6).

ANTICIPATION

ISSUE

Claims 1-6, 12, and 13 stand rejected under 35 U.S.C. § 102(b) as anticipated by Pestes (Ans. 4).

The Examiner cites Pestes as disclosing a flexible probe "having a diameter that is sized to access a breast duct and a distal portion being capable of contacting an interior lumen of a breast duct and retrieving a sample of the breast duct fluid from within the duct for analysis" (*id*). The Examiner states that Pestes' probe "is rigid before entry into the breast duct, and flexible upon resistance into the duct" (*id.* (citing Pestes, col. 2, ll. 16-25

[1] Although the Examiner includes claims 26 and 27 as part of the rejection over Pestes combined with Nicholson, the Examiner bases the obviousness conclusion on Pestes alone (*see* Ans. 5), and Appellant argues the rejection as being over Pestes alone (*see* App. Br. 10-13). We therefore consider the rejection of claims 26 and 27 separately from the rejection of claims 7, 8, and 10.

and 32-40)). The Examiner cites Hung as evidence that the diameter of Pestes' probe renders it "capable of performing the function as set forth in claim 1" (*id.*).

Appellant contends that Pestes' probe fails to meet the limitation of claim 1 requiring that the probe be "rigid before entry into the breast duct, and flexible upon resistance in the duct" (App. Br. 3), and that Pestes therefore "cannot anticipate independent claim 1" (*id.* at 5). Appellant contends that Pestes does not anticipate claim 6, because Pestes "does not teach or suggest a surface having molecules affixed that bind an agent in the ductal fluid" (App. Br. 6). Appellant contends that Pestes does not anticipate claim 13, because Pestes "does not teach or suggest a probe [which] comprises a shape memory material" (App. Br. 7). Appellant does not argue any claims separately other than claims 1, 6, and 13.

The issue with respect to this rejection, then, is whether the Examiner erred in finding that Pestes meets all of the limitations recited in claims 1, 6, and 13.

FINDINGS OF FACT ("FF")

1. Claim 1 recites a probe for collecting breast duct fluid from a breast duct to detect breast cancer or precancer. The probe's diameter is sized to access a breast duct and its distal portion is capable of contacting an interior lumen of a breast duct and retrieving a sample of the breast duct fluid for analysis. The probe may not have an opening through which fluid from an external source can be passed through the probe into the breast duct.

The probe must be "rigid before entry into the breast duct, and flexible upon resistance in the duct."

2. Claim 6 recites "[a] device as in claim 1, wherein the distal portion comprises a surface having molecules affixed that bind an agent in the ductal fluid it contacts."

3. Claim 13 recites "[a] device as in claim 1, wherein the probe comprises a shape memory material."

4. The Specification states:

> The probe can be made of a material that provides that it is rigid before entry into the breast duct, and that it then becomes flexible upon residence in the duct. Thus, the probe can be made of a thermo-sensitive polymer that is stiff at room temperature, and which softens and become[s] flexible at body temperature. This feature provides a probe that can reside in a duct over a period of time exceeding an office visit, e.g. for several hours, or several days, or several weeks. The residence feature allows for the collection and sampling of a sufficient quantity of ductal fluid for making a particular analysis. An example of material that the probe can comprise to achieve this feature is a shape memory material, such as, for example a nickel titanium alloy material.

(Spec. 8.)

5. Pestes discloses:

> A swab for collecting cell samples from a male urethra including a unitary elongate shaft having a constant diameter cylindrical handle at one end and a tapered circular cross-sectioned probe at the other end. The shaft is injection molded from a glass filled nylon material with the fiberglass being between 5 and 20 percent by volume and preferably being 10

> percent by volume. A fiber tip is mounted at the end of the probe to collect cell specimens.

(Pestes, abstract.)

6. Pestes discloses that "the distal extremity . . . of the probe has a diameter of 0.035 inches" (Pestes, col. 2, ll. 15-16). Pestes states that the disclosed general shape of the probe "permits injection molding of a one-pieced shaft from a particular material that provides the necessary combination of ductility, stiffness and tip size" (*id.* at col. 2, ll. 22-25).

7. Pestes discloses that "the swab shaft must be ductile enough so that it will not break and yet be stiff enough that it will not flex excessively during use" (Pestes, col. 1, ll. 18-20). Pestes discloses that:

> In order to provide sufficient ductility that the shaft will not break in use and still be stiff enough to prevent it from being bent during its intended use, the fiberglass must constitute 5 to 20 percent of the volume of the shaft. Ideally, the fiberglass would constitute 10 percent of the shaft.

(Pestes, col. 2, ll. 32-37).

8. Hung discloses "methods and apparatus for ablating or inhibiting the proliferation of epithelial and other cells lining a breast duct" (Hung, col. 1, ll. 17-19). Hung discloses "[a]n exemplary catheter . . . suitable for accessing ductal lumens for both diagnosis and therapy" that has an "outer tip diameter . . . about 0.8 mm" (*id.* at col. 10, ll. 54-61).

PRINCIPLES OF LAW

"To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either explicitly or inherently." *In re*

Schreiber, 128 F.3d 1473, 1477 (Fed. Cir. 1997). During examination, the PTO must interpret terms in a claim using "the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in the applicant's specification." *In re Morris*, 127 F.3d 1048, 1054 (Fed. Cir. 1997).

However, "[a]bsent claim language carrying a narrow meaning, the PTO should only limit the claim based on the specification or prosecution history when those sources expressly disclaim the broader definition." *In re Bigio,* 381 F.3d 1320, 1325 (Fed Cir. 2004). Thus, "while it is true that claims are to be interpreted *in light of* the specification and with a view to ascertaining the invention, it does not follow that limitations from the specification may be read into the claims." *Sjolund v. Musland*, 847 F.2d 1573, 1581 (Fed. Cir. 1988).

ANALYSIS

We agree with the Examiner that Pestes discloses all of the limitations in claims 1, 6, and 13. With respect to claim 1, we detect no error in the Examiner's finding that, based on the diameter of Hung's breast duct probe (*see* FF 8), the 0.035 inch diameter of Pestes' urethral probe (*see* FF 6) has a diameter suitable for probing breast ducts. Thus, given the configuration and size of Pestes' probe (*see* FF 5-7), we agree with the Examiner's finding that it would be capable of contacting an interior lumen of a breast duct and retrieving a sample of the breast duct fluid for analysis.

Appellant argues that the Examiner erred in finding that Pestes meets the limitation in claim 1 requiring the probe to be "rigid before entry into the breast duct, and flexible upon resistance in the duct" (App. Br. 3-4). Specifically, Appellant argues that because Pestes discloses that its probe is stiff enough such that it will neither break nor bend during use, "[c]learly, not all of the functional features of the present invention are disclosed in Pestes" (*id.* at 5).

We are not persuaded by these arguments, nor do we agree with Appellant's interpretation of Pestes. Rather, we agree with the Examiner that the disputed limitation in claim 1 is broad enough to encompass Pestes' probe.

We note that Appellant's Specification discloses embodiments in which a material such as a temperature sensitive polymer can be used to make a probe that is "stiff at room temperature, and which softens and become[s] flexible at body temperature" (Spec. 8 (FF 4)). However, it is well settled that it is improper to read limitations from the Specification into the claims. *See Sjolund v. Musland*, 847 F.2d at 1581.

Moreover, claim 1 does not, by its terms, limit the probe's flexibility based on temperature in the manner described in the Specification. Nor does claim 1 place any empirical limitation or absolute value on the probe's flexibility. Rather, claim 1 uses the relative terms "stiff" and "flexible," and only requires the probe to be "flexible upon resistance in the duct."

We therefore agree with the Examiner that claim 1 encompasses a fairly stiff probe that will flex, even a small amount, when it encounters

resistance in a breast duct. Because Pestes discloses that its probe is stiff, i.e., rigid, enough to be used as a probe, but also ductile, i.e., flexible, enough to avoid breaking when in use (*see* FF 5-7), we also agree with the Examiner that the limitation in claim 1, requiring the probe to be "rigid before entry into the breast duct, and flexible upon resistance in the duct," is broad enough to encompass Pestes' probe.

We therefore affirm the Examiner's anticipation rejection of claim 1 over Pestes. Because claims 2-5 and 12 were not argued separately from claim 1, they fall with claim 1. *See* 37 C.F.R. § 41.37(c)(1)(vii).

Appellant argues that Pestes "does not teach or suggest a surface having molecules affixed that bind an agent in the ductal fluid" and, therefore, does not anticipate claim 6 (App. Br. 6). We do not agree.

Pestes discloses that its probe has a "fiber tip . . . mounted at the end of the probe to collect cell specimens" (Pestes, abstract (FF 5)). Because the molecules in the fiber tip must bind to cells to collect and retrieve them from the urethra, we agree with the Examiner that Pestes meets the limitations of claim 6. We therefore affirm the Examiner's anticipation rejection of claim 6 over Pestes.

With respect to claim 13, Appellant argues that Pestes "does not teach or suggest a probe compris[ing] a shape memory material. The materials disclosed in Pestes *et al.* are nylon and fiberglass, neither of which are shape memory materials" (App. Br. 7).

In response, the Examiner cites Butler and Raynor as evidence that "fiberglass may be manufactured to be highly flexible or rigid," and cites

Jones and Kurz as evidence that "nylon may be manufacture[d] to be highly flexible or rigid. These ranges of flexibility or rigidity of fiberglass and nylon show that devices may be manufactured to a sufficient rigidity such that it would exhibit shape memory qualities" (Ans. 7).

We agree with the Examiner that the language "shape memory material" in claim 13 encompasses Pestes' flexible nylon/fiberglass probe. Appellant points to no definition or evidence, either in the Specification or the prior art, to support the assertion that nylon and fiberglass are not shape memory materials. While the Specification provides an example of a nickel titanium alloy as a shape memory material (Spec. 8 (FF 4)), as noted above, preferred embodiments are not to be read from the Specification into the claims. *See In re Bigio,* 381 F.3d at 1325.

Moreover, because Pestes discloses that its probe is stiff, i.e. rigid, enough to be used as a probe, but also ductile, i.e. flexible, enough to avoid breaking when in use (*see* FF 5-7), one of ordinary skill in the art would reason that Pestes' probe would return to its original shape after bending or flexing. Thus, when the term "shape memory material" is given its broadest reasonable interpretation consistent with the Specification, we agree with the Examiner that claim 13 encompasses Pestes' probe. We therefore affirm the Examiner's anticipation rejection of claim 13 over Pestes.

OBVIOUSNESS -- PESTES ALONE

ISSUE

Claims 26 and 27 stand rejected under 35 U.S.C. § 103(a) as being obvious in view of Pestes alone (Ans. 5).

The Examiner cites Pestes as disclosing the device recited in claims 26 and 27, "except for a probe diameter between 0.008 cm to about 0.045 cm. Pestes discloses a probe with a diameter of 0.08 cm" (Ans. 5). The Examiner contends that "it would have been an obvious matter of design choice to a person of ordinary skill in the art to vary the diameter of the probe, since it would only involve a mere change in the size of a component" (*id.*). The Examiner also finds that "[o]ne of ordinary skill in the art, furthermore, would have expected Appellant's invention to perform equally well with a diameter of 0.08 cm. Therefore, such a change in size is considered to be well within the level of skill of the ordinary artisan" (*id.*).

Appellant contends that the significantly larger diameter of Pestes' probe compared to the claimed probe "would make it impractical to be used as a device to retrieve fluid from a breast duct" (App. Br. 11). Appellant also contends that the Examiner's conclusion of obviousness is erroneous because the claimed probe and Pestes' probe are directed to different fields of medicine, and that, therefore, "it is not correct to assume that the issues relating to collecting cells from a male urethra are reasonably pertinent to the issues relating to collecting fluid from a female breast duct" (*id.* at 12-13). Appellant does not present separate arguments with respect to claims 26 and 27.

The issue with respect to this rejection, then, is whether the Examiner erred in concluding that one of ordinary skill would have considered a probe having the diameter recited in claim 26 obvious in view of Pestes' probe.

FINDINGS OF FACT

9. Claim 26 recites "[a] device as in claim 1, wherein said diameter of said probe is between about 0.008 cm and about 0.040 cm."

10. Regarding the dimensions of its probe, Pestes discloses:

> The preferred embodiment of the shaft has an overall length of slightly less than six inches and the probe covers about one quarter of this length. The preferred diameter of the handle is approximately 0.100 inches and the distal extremity **18** of the probe has a diameter of approximately 0.035 inches. While the foregoing configuration is preferred in order to provide an instrument that is properly balanced for ease of use, a handle size that is easy to hold and will not inadvertently break or unnecessarily bend, a considerable amount of dimensional variation is acceptable.

(Pestes, col. 2, ll. 11-21.)

Appellant states that Pestes' probe diameter of 0.035 inches is equivalent to 0.089 centimeters (App. Br. 11).

11. Pestes states the following regarding the process of collecting cell samples from a patient's urethra:

> This process has inherent difficulties with respect to males due to the small size of the urethra and the sensitivity surrounding its opening. First of all the probe end of the swab shaft must be small enough that when covered with the fiber tip that is used to capture cells it will fit comfortably in the urethra. At the same time the handle at the other end of the swab shaft must be sufficiently large to allow it to be firmly gripped.

(Pestes, col. 1, ll. 13-18.)

PRINCIPLES OF LAW

> In proceedings before the Patent and Trademark Office, the Examiner bears the burden of establishing a prima facie case of obviousness based upon the prior art. "[The Examiner] can satisfy this burden only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references" (footnote omitted).

In re Fritch, 972 F.2d 1260, 1265 (Fed. Cir. 1992) (citations omitted, bracketed material in original). Furthermore, "[e]ven when obviousness is based on a single prior art reference, there must be a showing of a suggestion or motivation to modify the teachings of that reference." *In re Kotzab*, 217 F.3d 1365, 1370 (Fed. Cir. 2000).

Regarding the showing required to establish obviousness, the Supreme Court, emphasizing a flexible approach to the question, has stated that the analysis "need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007). The Court has further advised that "[a] person of ordinary skill is . . . a person of ordinary creativity, not an automaton." *Id.* at 1742.

Regarding hindsight reasoning, the Court stated that "[a] factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning. Rigid preventative rules that deny factfinders recourse to common sense, however,

are neither necessary under our case law nor consistent with it." *Id.* at 1742-1743 (citations omitted).

Moreover, "[w]here 'the difference between the claimed invention and the prior art is some range or other variable within the claims . . ., the [applicant] must show that the particular range is critical, generally by showing that the claimed range achieves unexpected results.'" *Iron Grip Barbell Co., v. USA Sports, Inc.,* 392 F.3d 1317, 1322 (Fed. Cir. 2004) (quoting *In re Woodruff,* 919 F.2d 1575, 1578 (Fed. Cir. 1990)); *see also Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 1349 (Fed. Cir. 1984) (claimed device that differed from the prior art with respect to dimensional limitations but performed and operated in the same manner as the prior art device held obvious).

ANALYSIS

We agree with the Examiner that a person of ordinary skill in the art would have considered a probe having the diameter recited in claim 26 obvious in view of Pestes. We note that the upper limit of the diameter range recited in claim 26, 0.040 centimeters, is a little less than half of Pestes' preferred probe diameter of 0.089 centimeters.

However, Pestes explicitly discloses that "a considerable amount of dimensional variation is acceptable" outside of the preferred dimensions for its probe (Pestes, col. 2, ll. 20-21 (FF 10)). Given this teaching, we agree with the Examiner that one of ordinary skill in the art would have reasoned that Pestes' probe would acceptably perform its intended function with the diameter recited in claim 26.

Moreover, one of ordinary skill in the art, being a person of ordinary creativity and common sense, *see KSR*, 127 S. Ct. 1742-43, being aware that the dimensions of Pestes' probe could be varied considerably, and also aware of the small size and sensitivity of the male urethra (FF 11), would have reasonably inferred that reducing the diameter of Pestes' probe would be desirable in order to minimize the probe's intrusiveness. We therefore also agree with the Examiner that one of ordinary skill would have considered it obvious to provide Pestes' probe with the diameter recited in claim 26.

Appellant argues that the tip of Pestes' probe is "actually much larger [than 0.089 centimeters] due to the fiber tip which surrounds the distal end of the device," and that "[t]herefore, the overall diameter of the probe described in Pestes *et al.* would make it impractical to be used as a device to retrieve fluid from a breast duct" (App. Br. 11). Moreover, Appellant argues, given the taper of Pestes' probe, inserting it into a breast duct "may be successful for the very tip of the probe (assuming no fiber tip), however, as the probe is inserted deeper into the ductal canal, the increased diameter of the probe (to a maximum of 0.254cm) would cause considerable pain to the patient as well as potentially causing damage to the ducts themselves" (*id.* at 11-12).

Appellant further urges that Pestes' examination of the male urethra is a "completely different problem[]" than examining breast ducts (*id.* at 12), and that "because the problems concerning artisans relying on the disclosure in Pestes et al. are not pertinent to the problems concerning the present

disclosure, artisans lack the required motivation to combine them in a manner that renders the claimed invention obvious" (*id.* at 13).

We are not persuaded by these arguments. Claim 26 is directed to a probe having specific properties, not a method of its use. The relevant issue with respect to this rejection, therefore, is not whether one of ordinary skill in the art would have been motivated to use Pestes' probe, as disclosed, to collect samples from breast ducts. Rather, the issue is whether a probe having the diameter recited in claim 26 would have been obvious in view of Pestes' probe.

As discussed above, although Pestes' probe has a diameter slightly more than twice that recited in claim 26, one of ordinary skill in the art would have reasoned from Pestes' teachings (FF 10) that a probe with a significantly smaller diameter would function acceptably as a urethral probe, and would also have inferred that a narrower probe would be desirable, given the size and sensitivity of the male urethra (FF 11). Moreover, while Pestes' probe may be intended as a urethral probe rather than a breast duct probe, a claim must be considered prima facie obvious when the prior art suggests its practice, even if the prior art's reason for practicing the claimed subject matter is different than the applicant's. *See KSR*, 127 S. Ct. at 1741-1742 ("In determining whether the subject matter of a patent claim is obvious, neither the particular motivation nor the avowed purpose of the patentee controls. What matters is the objective reach of the claim. If the claim extends to what is obvious, it is invalid under § 103.")

Thus, we do not agree with Appellant that the probe diameter recited in claim 26 would have been unobvious over Pestes. We therefore affirm the Examiner's rejection of claim 26 as obvious over Pestes. Because claim 27 was not argued separately, it falls with claim 26. *See* 37 C.F.R. § 41.37(c)(1)(vii).

OBVIOUSNESS -- PESTES AND NICHOLSON

ISSUE

Claims 7, 8, and 10 stand rejected under 35 U.S.C. § 103(a) as being obvious in view of Pestes and Nicholson (Ans. 5).

The Examiner concedes that Pestes does not disclose a probe with "a means (marker/indicia) to measure a quality of the ductal fluid *in situ*," and cites Nicholson to meet that limitation (*id.* (citing Nicholson, col. 4, ll. 12-17)). The Examiner contends that one of ordinary skill in the art would have considered it obvious "to modify the distal portion of Pestes with the m[e]ans to measure a quality of the ductal fluid, as taught by Nicholson, for providing markings to indicate the depth of the device distal end when anchored. It is noted that Appellant indicates that such quality/means can comprise a marker" (*id.* (citing Spec. 4:8)).

Appellant argues that the Examiner has not established that the rejected claims would have been obvious over the cited references because the term "marker" is defined in the Specification as meaning biological rather than physical indicia (App. Br. 8-9), and because the depth measurement provided by Nicholson's device is not properly considered a quality (*id.* at 9-10).

The issue with respect to this rejection, then, is whether the Examiner has shown that the cited references would have rendered claims 7, 8, and 10 obvious to one of ordinary skill in the art.

FINDINGS OF FACT

12. Claims 7, 8, and 10 read as follows:

> 7 A device as in claim 1, wherein the distal portion comprises a means to measure a quality of the ductal fluid *in situ*.
>
> 8 A device as in claim 7, wherein the quality comprises an indicia selected from the group consisting of cell size, cell density, nuclear size, nucleoli size, and chromatin coarseness.
>
> 10 A device as in claim 7, wherein the quality comprises a marker.

13. The Specification discloses:

> The agent or marker sought in the ductal fluid can be, e.g. a molecule such as an antibody, a peptide, a polypeptide, a nucleic acid, a polynucleotide, a small organic molecule, a macromolecule, a polymer, a carbohydrate, or a lipid. In general any marker characteristic of ductal precancer or cancer can be used, provided it is retrievable by the probe.

(Spec. 10.)

14. Nicholson discloses a device for "detection and location of presymptomatic, non-palpable lesion[s] within the female breast" (Nicholson, col. 1, ll. 8-10). Nicholson's device consists of a needle cannula with a probe wire inside it (*id.* at col. 2, ll. 41-56). To locate lesions in the breast, the device is "inserted into the body tissue to a location whereat the

distal end lies hopefully at about 2 cm from the lesion as previously determined by mammography" (*id.* at col. 2, ll. 56-59). The device's location adjacent to the lesion is confirmed by repeating the mammography, and the needle sheath is removed, leaving the wire probe in the tissue as a marker to indicate the lesion's location to the surgeon (*see id.* at col. 2, l. 59, through col. 3, l. 62).

15. Nicholson discloses that its wire probe is advantageous in that it is made of a memory shape material that can be shaped like a hook to maintain its location in the breast tissue, but is flexible enough to be dislodged and repositioned without breaking, unlike previous probe wires (Nicholson, col. 3, ll. 4-19; *see also* Figures 2 and 3). Nicholson does not specifically mention that its probe is suitable for examining breast ducts.

16. Nicholson discloses:

> Graduations **26** are provided on the proximal extent of the probe wire. These markings indicate both the depth of the probe wire's distal end when anchored and the depth of the probe unit's distal end when the wire is properly sheathed in the cannula.
>
> Graduations **28** on the extended distal portion of the probe wire are an indication to the surgeon as to relation of incision to the distal end of the wire.

(Nicholson, col. 4, ll. 12-19.)

PRINCIPLES OF LAW

As the Supreme Court recently pointed out, "it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention

does . . . because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." *KSR Int'l v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007). Thus, "[i]n determining whether obviousness is established by combining the teachings of the prior art, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art." *In re GPAC Inc.*, 57 F.3d 1573, 1581 (Fed. Cir. 1995) (internal quotations omitted).

When evaluating claims for obviousness, "the prior art as a whole must be considered. The teachings are to be viewed as they would have been viewed by one of ordinary skill." *In re Hedges*, 783 F.2d 1038, 1041 (Fed. Cir. 1986). Moreover, "'[i]t is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art.'" *Id.* (quoting *In re Wesslau*, 353 F.2d 238, 241 (CCPA 1965)).

ANALYSIS

We agree with Appellant that the Examiner has not made out a prima facie case of obviousness based on Pestes and Nicholson.

Pestes discloses that its probe is to be used to collect samples from a male urethra (FF 5, 11). Nicholson discloses that the hook-shaped wire on its probe is configured to be deployed into breast tissue and maintained at a specific location, to designate to a surgeon the location of a lesion to be

excised (*see* FF 14). We do not see, and the Examiner does not explain, where the references would have suggested to one of ordinary skill that it would be desirable to provide Pestes' urethral probe with a wire that is intended to be maintained within breast tissue to indicate the location of lesions.

Even assuming for argument's sake that Pestes' probe is suitable for examining breast ducts, we do not see, and the Examiner does not point to, any specific disclosure in Nicholson suggesting that its wire probe would be desirable on a breast duct probe having a fiber tip like Pestes' probe. We do not agree with the Examiner that one of ordinary skill examining breast ducts with Pestes' probe would have considered it desirable to exchange Pestes' cell-collecting fiber tip for a hook-shaped wire probe configured to maintain its position in breast tissue. We therefore do not agree with the Examiner that one of ordinary skill would have been prompted to combine the Pestes and Nicholson disclosures.

Regarding the gradations on Nicholson's probe wire, the Examiner argues that in addition to being used to measure the probe's depth "[i]t is also possible that these markings provide a scale to measure . . . cell size. If cell size is an indicator of a quality of ductal fluid as suggested by Appellant's claim 8, then markings suggested by Nicholson is certainly a means to measure a qualitative aspect of ductal fluid" (Ans. 8).

We are not persuaded by this argument. The Examiner points to nothing in Nicholson disclosing or suggesting that the gradations were of a suitable size or configuration for measuring cells.

Because we do not agree with the Examiner that one of ordinary skill in the art would have been prompted to combine Pestes and Nicholson in the manner advanced by the Examiner, we reverse the Examiner's obviousness rejection of claims 7, 8, and 10 over those references.

OBVIOUSNESS -- PESTES AND MARCHOSKY

ISSUE

Claim 11 stands rejected under 35 U.S.C. § 103(a) as being obvious in view of Pestes and Marchosky (Ans. 6).

The Examiner concedes that Pestes does not disclose a probe having "a coating of an anesthetic on the exterior of the probe" as recited in claim 11, and cites Marchosky to meet that limitation (Ans. 6). The Examiner contends that one of ordinary skill in the art would have considered it obvious "to modify the device of Pestes with the coating taught by Marchosky to relieve pain in the treatment of tumors particularly in the breast area" (*id.* (citing Marchosky, col. 5)).

Appellant contends that "[t]here is no clear, particular motivation in the references to reach the claimed invention" (App. Br. 17).

The issue with respect to this rejection, then, is whether the Examiner has shown that the cited references would have rendered claim 11 prima facie obvious to one of ordinary skill in the art.

FINDINGS OF FACT

17. Claim 11 recites "[a] device as in claim 1, further comprising a coating of an anesthetic on the exterior of the probe."

18. Marchosky discloses an "apparatus for treating tissue interstitially with multiple modalities of treatment" (Marchosky, col. 3, ll. 7-9). Marchosky's apparatus includes a hollow probe that provides the different treatment modalities directly to the treatment site, for example a tumor (*id.* at col. 3, ll. 9-14). Thus, for example, in addition to applying a chemotherapeutic agent to a tumor, the probe can also enhance the medicament's activity by applying heat to the tumor with a heating element (*id.* at col. 3, ll. 14-25).

19. Marchosky discloses that the probe may also carry "an anesthetic or analgesic for relieving pain. An anesthetic or analgesia is particularly helpful to relieve pain in the treatment of tumors particularly in sensitive areas such as the breast" (Marchosky, col. 5, ll. 33-37).

ANALYSIS

We agree with the Examiner that one of ordinary skill in the art would have considered claim 11 prima facie obvious in view of Pestes and Marchosky. A person of ordinary skill, advised by Pestes of the sensitivity of the urethral area examined by its probe (FF 11), and further advised by Marchosky of the desirability of using anesthetic on probes used in sensitive areas (FF 19), would have been prompted to include an anesthetic on Pestes' probe to alleviate the potential discomfort occurring upon examining the urethra.

Appellant argues that the Examiner failed to provide the specific motivation required to establish a prima facie case of obviousness (App. Br. 14-17). We are not persuaded by this argument.

As discussed above, the Supreme Court has rejected a rigid approach to the obviousness question, stating that the analysis under § 103 "need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007). The Court further advised that "[a] person of ordinary skill is . . . a person of ordinary creativity, not an automaton." *Id.* at 1742.

As also pointed out above, the Supreme Court stated that "[a] factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning. Rigid preventative rules that deny factfinders recourse to common sense, however, are neither necessary under our case law nor consistent with it." *Id.* at 1742-1743 (citations omitted).

Because a person of ordinary creativity and common sense, *see KSR*, 127 S. Ct. at 1742-43, would have been prompted to include an anesthetic on Pestes' probe to alleviate the potential discomfort occurring upon examining the urethra, we do not agree with Appellant that the prior art fails to provide a reason for combining the references. We therefore affirm the Examiner's obviousness rejection of claim 11.

SUMMARY

We affirm the Examiner's rejection of claims 1-6, 12, and 13 under 35 U.S.C. § 102(b) as anticipated by Pestes.

We affirm the Examiner's rejection of claims 26 and 27 under

35 U.S.C. § 103(a) as being obvious in view of Pestes alone.

We reverse the Examiner's rejection of claims 7, 8, and 10 under 35 U.S.C. § 103(a) as being obvious in view of Pestes and Nicholson.

We affirm the Examiner's rejection of claim 11 under 35 U.S.C. § 103(a) as being obvious in view of Pestes and Marchosky.

AFFIRMED-IN-PART

clj

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